



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

September 18, 1998

MEMORANDUM

EPA Reg. No. 49538-2 PHYTON-27
DP Barcode: D246592
Case No: 027581

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
9/18/98
JCR

To: Janet Whitehurst/Cynthia Giles-Parker, PM 22
Fungicide Branch
Registration Division (7505C)

Registrant: Source Technology Biologicals Inc.

ACTION REQUESTED: Review of a package (which includes primary eye irritation and dermal irritation studies conducted on a 0.5% v/v dilution of this product in distilled water). The registrant is asking that the label-specified re-entry interval be revised from 24 hours to 12 hours.

COMMENTS AND RECOMMENDATIONS: The two studies (a primary eye irritation study in MRID 44539302 and a primary dermal irritation study in MRID 44539301) are acceptable, and indicate that a 0.5% dilution of the product in water (according to the registrant's cover letter dated March 18, 1998 a 5,000 ppm concentration of the product is the "maximum use rate.") is in toxicity category IV in terms of eye and dermal irritation potential (although the undiluted product is in toxicity category I by these exposure routes).

The following is the acute toxicity profile of EPA Reg. No. 49538-2 PHYTON-27, based on information in the tox oneliners (the studies are "cited" as no indication was given in the material sent to TRB as to whether or not product-specific studies for this formulation have ever been submitted to the Agency):

Acute Oral LD50	II	Cited
Acute Dermal LD50	III	Cited
Acute Inhalation LC50	IV*	Cited*
Primary Eye Irritation	I	Cited
Primary Dermal Irritation	I	Cited
Dermal Sensitization	Yes	Cited
Primary Eye (use dilution)	IV	Acceptable
Primary Dermal (use dilution)	IV	Acceptable

*Byron's
Winkler's
respirator
or
safety goggles
w/ face shield #5*

*This is based on the statement in the registrant's letter that "The absence of an LD₅₀ for inhalation in the acute toxicity studies is due to the inability to keep a dose lethal to rats suspended. EPA Worker Protection Safety requirements do not include wearing a respirator."

It is noted that, for the purposes of this action, TRB has not reviewed the cited studies as to their acceptability.

The following is the appropriate precautionary labeling for this product, based on the acute toxicity profile given above, and as obtained from the Label Review System:

Date: 09/18/98 LABEL REVIEW SYSTEM

ID #: 049538-00002 Phyton-27

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to eye irritation, dermal irritation toxicity categories.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

*Why now
what
trigger
Eye irritate
Respirator*

AGRICULTURAL USE REQUIREMENTS:

DIRECTIONS FOR USE:

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water,

*WPS
Then
Dermal III
Eye II*

wear: coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear, Wear goggles or face shield, and waterproof gloves.

SIGNAL WORD: DANGER PELIGRO

PRECAUTIONARY STATEMENTS:

Corrosive. Causes irreversible eye damage or skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear, goggles or face shield and waterproof gloves. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

OR

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Date: 09/18/98

LABEL REVIEW SYSTEM

ID #: 049538-00002 Phyton-27

NOTE TO PHYSICIAN:

The proposed label should contain a Note to Physicians. Some suggested types of information include the following:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Probable mucosal damage may contraindicate the use of gastric lavage.

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As the registrant has demonstrated that the product, as diluted for use, is in toxicity category IV in terms of its dermal and eye irritation potentials, we can accept additional modifying precautionary labeling statements such as the following:

-After product is diluted in accordance with the directions for use, goggles or face shield are not required.

-If product, diluted in accordance with the directions for use, gets on skin, medical attention is not required.

It is noted that the above statements do not specify the re-entry period. TRB can make no recommendations with respect to a change in the re-entry interval. This can only be done by HED.

DATA EVALUATION REPORT

PHYTON - 27

STUDY TYPES: PRIMARY EYE IRRITATION - RABBIT (81-4)
PRIMARY DERMAL IRRITATION - RABBIT (81-5)

SUMMARY: ACUTE TOXICITY ONE-LINERS (81-4, 81-5)

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
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Primary Reviewer:
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Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
LeeAnn Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400, formerly §81-4)

Product Manager: 22
MRID No.: 44539302

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Report Dated: May 15, 1987
Study No.: 87-0914-21 (B)

Testing Facility: Hill Top Biolabs, Inc.
Author: Doyle, R.L.

Quality Assurance (40 CFR §160.12): Included

Test Material: Phytol -27; brown liquid
Dosage: 0.1 mL of 0.5% v/v test material in distilled water
Species: Rabbits; Albino, New Zealand White
Age: Young adult
Weight: Not reported
Source: Clerco Research Farm

Conclusion:

1. **Toxicity Category:** IV (Slight irritant)
2. **Classification:** Acceptable

Procedure (including deviations from 870.2400): One rabbit with naturally occurring opacity should have been excluded from the study.

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
	Unwashed eyes			
Corneal Opacity	0/5	0/5	0/5	0/5
Iritis	0/5	0/5	0/5	0/5
Conjunctivae:				
Redness ¹	3/5	0/5	0/5	0/5
Chemosis ¹	0/5	0/5	0/5	0/5
Discharge	0/5	0/5	0/5	0/5

¹Score of 2 or greater considered a positive response.

The incidences given above exclude the rabbit which had "naturally occurring opacity" before the test material was administered.

Summary: No corneal opacity was noted on any rabbits except one with natural occurring opacity that should have been excluded from the study. No iritis was noted on any rabbits. Conjunctival redness (scores ≥ 2) was noted on 3/6 rabbits at one hour after test material instillation; all scores were zero at 48 hours.

Special Comment: The test material used was a 0.5% dilution of the registered product, so the results of this study do not affect the basic precautionary labeling.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500, formerly §81-5)

Product Manager: 22
MRID No.: 44539301

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Report Dated: June 4, 1987
Study No.: 87-0914-21 (A)

Testing Facility: Hill Top Biolabs, Inc.
Author: Doyle, R.L.

Quality Assurance (40 CFR §160.12): Included (p. 15)

Test Material: Phytol -27; brown liquid
Dosage: 0.5 mL of 0.5% v/v test material in distilled water
Species: Rabbits; Albino, New Zealand White
Age: Not reported
Weight: Not reported
Source: Clerco Research Farm

Conclusion:

1. **Toxicity Category:** IV (Slight irritant)
2. **Classification:** Acceptable

Procedure: (including deviations from 870.2500): "The test material, diluted to 0.5% v/v with distilled water, was applied to a small surgical-gauze patch, approximately 1 inch x 1 inch, two layers thick. This patch was then applied to one intact skin site on each of the six test animals. Each animal received 0.5 mL of test material. The application sites were rotated to minimize bias due to site-to-site variation."

Results: PDIS = 0.6 (Slight irritant). Thirty minutes to one hour after patch removal, very slight erythema (maximum score = 1) was noted on 4/6 rabbits. Six rabbits had very slight erythema (maximum score = 1) at 24 hours and five rabbits had very slight erythema (maximum score = 1) at 48 hours. By 72 hours, there was no irritation on any of the rabbits. Yellow stain on the fur was noted on all rabbits throughout the study.

Special Comments: According to the report (MRID 44539301) the test material used was not the actual product, but a 0.5% v/v dilution of the product with distilled water. Therefore, the toxicity category IV classification refers (see the attached cover letter of March 18, 1998, from the registrant) to the "maximum use rate" or 5,000 ppm concentration.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D246592
2. PC CODE: 024401
3. CURRENT DATE: August 7, 1998
4. TEST MATERIAL: Phytol - 27; brown liquid; these studies were conducted on a 0.5% v/v dilution of the formulated product in water.

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Primary eye irritation rabbit/Hill Top Biolabs, Inc., 87-0914-21(B) /JUN-4-1987	44539302	Slight irritant; no corneal opacity and iritis; conjunctival redness on 3/5 rabbits at 1 hour; resolved by 24 hours. Material tested was a 0.5% v/v dilution of product in water.	IV	A
Primary dermal irritation rabbit/ Hill Top Biolabs, Inc., 87-0914-21(A) /JUN-4-1987	44539301	Slight irritant; very slight erythema on 4/6, 6/6, and 5/6 rabbits at 1, 24, and 48 hours, respectively; all cleared of irritation by 72 hours. Material tested was a 0.5% v/v dilution of product in water.	IV	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated